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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,101	03/30/2001	Jason Pluta	DEX-0205	4789

26259 7590 07/30/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/30/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/823,101

Applicant(s)

PLUTA ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment filed 14 May 2002 (Paper No: 10) is acknowledged. Accordingly, claim 1 is amended, claims 2, 7-8, and 10-25 are cancelled, claims 1, 3-6, and 9 are pending and under examination.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 1st Withdrawn

3. Rejection of claims 1-6 and 9 under 35 U.S.C. 112, first paragraph is withdrawn in view of amendments.

Claim Rejections - 35 USC § 102 Maintained

4. Rejection of claims 1(b), 3-6, and 9 over Kato, et al., (1983) under 35 U.S.C. 102(b) is maintained for reasons set forth in the previous office action. The traversal is on the grounds that the Kato gene has only 92% identity similarity over only a portion of SEQ ID NO: 2 and the specification indicates that a sequence that hybridizes with the antisense sequence of SEQ ID NO: 2 must have at least 95% identity to SEQ ID NO: 2. Applicant's arguments have been considered but are not persuasive because the claims are broadly drawn to any nucleic acid that hybridizes (completely or partially) to the claimed antisense sequences and Kato teaches partial sequences that have 92% identity to SEQ ID NO: 2 that will hybridize under stringent conditions.

Maintained

New Claim Rejections - 35 USC § 112

5. Claim 9, as it reads on SEQ ID NO: 2, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Cancelled

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The nature of the invention is to a SSG of claim 1, which may be used in the diagnosis of stomach cancer. The specification indicates that SEQ ID NO: 2 is expressed in a variety of normal and cancer tissue (tables 3-4, p. 56-58) including but not limited to cancer. The specification does not give any guidance or exemplification of how SEQ ID NO: 2 may be used to diagnose stomach cancer when it is expressed in such a diverse array of tissue types. There is no guidance as to which assays/experiments may be used to diagnose stomach cancer using SEQ ID NO: 2. Accordingly, one of ordinary skill in the art would not know how to use SEQ ID NO: 2 to diagnose stomach cancer. In view of the lack of said teachings, working examples, and insufficient guidance as to how to use SEQ ID NO: 2 in the diagnosis of stomach cancer, it would be unpredictable to use the cell line and one of skill in the art would not be able to practice the claimed invention because undue experimentation would be required.

Claims 1, 3-6, and 9 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The nature of the invention is to SEQ ID NO: 2, which may be used in the diagnosis of stomach cancer. The claims are further drawn to vectors comprising the above sequence, host cells, a method of producing a polypeptide and a cell expressing a SSG polypeptide.

main

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The specification discloses SEQ ID NO: 2, which is a select clone from a cDNA PCR library that contains EST's from genes that are upregulated in stomach cancer (p. 51). Absent evidence to the contrary, SEQ ID NO: 2 is deemed to be an incomplete cDNA. Since the cDNA that corresponds to SEQ ID NO: 2 is not full-length, a sequence prepared from undefined parts of a cDNA clone will not comprise the entire coding region of any particular gene, nor is it clear that the partial sequence is even in frame to encode a polypeptide.

The instant disclosure of a single species of nucleic acid does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera including full-length genes. A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification does not provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of polynucleotides. There is no description of the conserved regions, which are critical to the structure and function of the genus claimed. Thus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed gene.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
July 26, 2002


SHEELA HUFF
PRIMARY EXAMINER